

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

<b>IN RE: BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2606</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>HON. ROBERT B. KUGLER CIVIL NO. 15-2606 (RBK)(JS)</b>

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**PLAINTIFFS' REPLY BRIEF IN FURTHER SUPPORT OF MOTION TO EXCLUDE  
GENERAL CAUSATION OPINIONS OF DEFENSE EXPERT KEITH WILSON, M.D.**

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### **PRELIMINARY STATEMENT**

Defendants' opposition to the motion to preclude the general causation opinions of Dr. Keith Wilson leaves no doubt that Defendants simply purchased a resume when they hired Dr. Wilson as an expert. Dr. Wilson is nothing more than a blank slate upon which Defendants inscribed the never published opinion that there is not general causation. Absent from the opposition is any explication of a real methodology underlying his complete rejection of the peer reviewed consensus that Olmesartan does cause OIE in some patients. Rather, the defense attempts to recast the actual record and create the illusion that Dr. Wilson, who had never heard of this condition before the defense hired him, actually considered studies and data that he explicitly excluded from his analysis.

In their desperation to keep Dr. Wilson in this case the defense retreats to claiming that the identification of huge gaps in his analysis goes only to the weight of the evidence and issues for cross-examination. In the face of a mountain of peer reviewed literature, the defense concedes that Dr. Wilson's unreliaibly restrictive personal criteria led him to the conclusion that he, "could not identify reliable scientific evidence to support an opinion that olmesartan **can cause** sprue-like enteropathy." (Defense brief at 1). This is very telling, inasmuch as the FDA looked at the issue, including epidemiological data, and concluded that Olmesartan **can cause** sprue-like enteropathy. The establishment of an unreachable personal standard designed to achieve a predetermined conclusion, combined with the failure to include important data, or to seriously contend with a scientific consensus, renders the methodology unsound, and inadmissible.

### **LEGAL ARGUMENT**

Defendants cannot defend Dr. Wilson's methodology, including his complete rejection of the peer reviewed scientific conclusion that Olmesartan causes sprue-like enteropathy, so they talk in general about his background in research, which they admit involves no consideration of the issue before the Court. The defense fails to point to any specific research Dr. Wilson has conducted on the question here, because there is none. In this regard, Defendants also admit to Dr. Wilson's failure to analyze or incorporate the celiac literature, which is closely analogous and highly relevant, without any legitimate explanation. (Defense brief at 14).

Defendants cannot remedy the key methodological flaws. This begins with Dr. Wilson's rejection of all dechallenges and rechallenges that do not arise from randomized, controlled studies. Dr. Wilson paid lip service to this data in a few isolated spots, but did make it clear that he did not credit this data at all. That is unreasonable, in light of the defense's admission that case reports are admissible, and, "probative of causation." (Defense brief at 11). Dr. Turner utterly fails to reliably account for the scientific data he ignored in his report, including for example the FDA's analysis and conclusions.

The Wilson test is so lacking in methodological balance that the defense admits it is grounded on studies that are admittedly "underpowered" to answer the question before the Court. However, the defense completely fails to address the fact that Dr. Wilson relied on the lack of proof of a causal association in underpowered studies such as ROADMAP and Greywoode. This is a significant methodological flaw since those studies do not scientifically answer the question. Of course, Dr. Wilson was never given and never considered or contended with the positive rechallenge documented in the ROADMAP study, fitting even his criteria, and found by Daiichi's internal physicians to be probably caused by Olmesartan. This was never provided to him, so he

did not weigh it – since this is exactly the type of evidence he says he weighs most heavily, this is a gaping methodological hole that cannot be filled by semantics.

Of significant note, Defendants' efforts to keep Dr. Wilson in the case validate the admissibility of the opinions of every one of Plaintiffs' experts. The constant fall back to the refrain that the issues raised go only to the weight, not admissibility of the evidence, must also apply to Plaintiffs' experts, who stand on solid methodological footing as they relied on and opine consistent with the peer reviewed consensus of causation. Defendants even acknowledge Dr. Wilson's concession that the peer reviewed literature is adequate to and does guide clinical practice in the diagnosis and treatment of OIE, with no legitimate scientific attack on this highly probative fact. (Defense brief at 12). Defendants also attack Dr. Stephen Lagana for failing to explicitly state in his report that he applied Bradford Hill, while acknowledging that Dr. Lagana was aware of this criteria and testified to application of certain Bradford Hill factors to support his opinion. Yet, Defendants argue here, where their own expert is in peril, that it is enough to apply the Bradford Hill criteria without explicitly discussing each factor. (Defense brief at 7).

**CONCLUSION**

For the foregoing reasons, and those set forth in Plaintiffs' initial brief, Dr. Keith Wilson should be precluded from testifying at trial.

Respectfully,

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